



OCT 10 2007

Oona A. Jackson
Novartis
Corporate Intellectual Property
One Health Plaza, Building 104
East Hanover, NJ 07936-1080

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,465,504

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,465,504, claims of which cover the human drug product EXJADE® (deferasirox), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 650 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 650 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 23, 2007, (72 Fed. Reg. 8180). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2103 - 1173) + 185 \\ &= 650 \text{ days (1.8 years)}\end{aligned}$$

Since the regulatory review period began July 31, 1999, before the patent issued (October 15, 2002), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From July 31, 1999, to and including October 15, 2002, is 1173 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,465,504
Granted:	October 15, 2002
Original Expiration Date ¹ :	July 24, 2017
Applicant:	René Lattmann and Pierre Acklin

¹Subject to the provisions of 35 U.S.C. § 41(b).

Owner of Record: Novartis AG

Title: SUBSTITUTED 3,5-DIPHENYL-1,2,4-TRIAZOLES
AND THEIR USE AS PHARMACEUTICAL
METAL CHELATORS

Product Trade Name: EXJADE® (deferasirox)

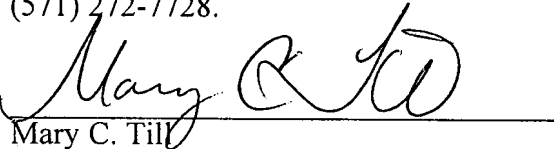
Term Extended: 650 days

Expiration Date of Extension: April 5, 2019

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7728
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to Raul Tamayo at (571) 272-7728.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

RE: EXJADE® (deferasirox)
FDA Docket No.: 2005E-0261

Attention: Beverly Friedman